EXHIBIT 56

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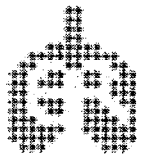

SERIES "ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING"
Edited by V. Brusasco, R. Crapo and G. Viegi
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General considerations for lung function testing

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their filter does not alter standard lung function measurements (vital capacity, FVC, FEV_1, PEF, mean forced expiratory flow between 25% and 75% of FVC, TLC and $D_{L,CO}$).

In the absence of evidence for infection transmission during pulmonary function testing, and the absence of a clear-cut benefit, the regular use of in-line filters is not mandated when the precautions described in the previous *Prevention* sections are followed.

Use of such filters is an area of controversy. On the one hand, some spirometric equipment, particularly those incorporated in multipurpose testing systems, employ valve manifolds, which are situated proximal to breathing tubes. These valve arrangements provide internal surfaces on which the deposition of expired aerosol nuclei is likely. Given their complexity, they may be difficult to disassemble and disinfect between subjects. To the extent that in-line filters have been shown to remove microorganisms from the expiratory air stream and, thus, prevent their deposition as aerosol nuclei on spirometer surfaces, their use may be indicated. On the other hand, in-line filters have been relatively inefficient in excluding microorganisms at the high flows often seen in pulmonary testing, and instrument contamination has been observed when filters have been used [17–20]. However, barrier filters with a high efficiency (>99%) for excluding bacteria have been reported [21, 22], but their performance in excluding smaller microorganisms such as viruses is unknown. A reduction in overall costs with in-line filters, as compared with a disinfection approach to hygiene, in a pulmonary laboratory has been reported [17].

The use of in-line filters does not eliminate the need for regular cleaning and decontamination of lung function equipment.

Equipment design

Manufacturers of lung function equipment are encouraged to focus on designs that can be easily disassembled for cleaning and disinfection. Purchasers of pulmonary function equipment are encouraged to inquire about cleaning and disinfection issues prior to purchase of an instrument, which should involve an evaluation of the ease of cleaning and the clarity of written instructions, and an understanding of what equipment and chemicals will be required.

Level of infection risk

Lung function equipment has not been directly implicated in the transmission of infections, although there is indirect evidence of infection transmission during pulmonary function testing. Organisms from the respiratory tract of test subjects have been recovered from mouthpieces and the proximal surfaces of tubing through which subjects breathe [19, 23]. The flows generated during spirometric manoeuvres may be high enough to aerosolise contaminant organisms, although such aerosolisation has not been demonstrated. There is one case report of a TB skin-test conversion following exposure to a spirometer previously used to test a patient with documented TB [24]. Likewise, there is circumstantial evidence that contaminated lung function equipment may be implicated in increasing the prevalence of *Burkholderia cepacia* infections among cystic fibrosis patients at one centre [25]. There is evidence that pneumotachometer-based systems are less susceptible to bacterial contamination than water-sealed spirometers [26]. In addition, it is well documented that community water supplies can be contaminated with *Mycobacteria* spp. and *Pseudomonas aeruginosa* organisms [27–29]. Thus, there is a potential for both patients/subjects and healthcare workers to deposit microorganisms onto spirometer surfaces (including mouthpieces, nose clips, tubing and any internal or external machine surface), which could subsequently come into direct or indirect contact with other patients or healthcare workers.

This does not pose an appreciable threat to patients/subjects/workers with competent immune systems. It has been argued that immunocompromised patients may require only a relatively small infective dose of either opportunistic organisms or common pathogens for infection to occur. However, there is no direct evidence that routine pulmonary function testing poses an increased risk of infection to immunocompromised patients.

Concerns for the protection of immunocompromised patients, along with increased public and provider awareness of hospital infection-control issues since the 1990s, has led many laboratory directors to routinely use in-line filters to reassure patients and laboratory personnel that their protection has been considered.

PERSONNEL QUALIFICATIONS AND TECHNICIAN'S ROLE IN QUALITY CONTROL

Personnel qualifications

Previously, the ATS has published recommendations for laboratory personnel conducting pulmonary function tests [30]. Minimum requirements include sufficient education and training to assure that the technician understands the fundamentals of the tests, the common signs of pulmonary diseases and the management of the acquired pulmonary function data. The ATS also recommended that medical directors should have appropriate training and be responsible for all pulmonary function testing [31]. Since these initial recommendations, pulmonary function testing equipment and procedures have become considerably more complex. The use of computers has reduced the need for routine manual measurement; however, new and more complex training issues have evolved. Many providers of pulmonary function training programmes have expanded the scope and length of training to accommodate these new needs.

The current guidelines suggest that completion of secondary education and at least 2 yrs of college education would be required to understand and fulfil the complete range of tasks undertaken by a pulmonary function technician.

For pulmonary function testing, an emphasis on health-related sciences (nursing, medical assistant, respiratory therapy, *etc.*) is desirable. Formal classroom-style training alone does not, however, establish competency in pulmonary function testing. Technicians who conduct pulmonary function testing need to be familiar with the theory and practical aspects of all commonly applied techniques, measurements, calibrations, hygiene, quality control and other aspects of testing, as well as having a basic background knowledge in lung physiology and pathology. In the USA, the National Institute for Occupational